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RESEARCH ARTICLE

An Improvement in Patient Compliance in Diabetes Mellitus

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ABSTRACT:
Diabetes is a complex disorder which requires constant attention to diet, exercise, glucose monitoring, and medication to attain better glycemic control. The main goals of diabetes care are good metabolic control, and minimization of complications which are modified by patient compliance - the extent to which a person's behavior coincides with medical or other health care regimen. Poor adherence to medication regimens is common, contributing to substantial deterioration of disease, mortality and increased health-care costs. Low adherence to treatments has resulted in poor outcomes, even when the treatment was a placebo. It was planned to determine improving patients compliance with blood glucose monitoring, dietary schedule and exercise in patients of DM. A prospective observational study was conducted in a Tertiary care hospital. Patients demographic and laboratory investigation was collected from case sheets for a period of 1 year. Patients were included in the study based on the following characters, 1)Patient who are diagnosed with diabetes mellitus with treatment of more than one medications, 2)Patient above 18 years of age, and 3)Patients who are willing to participate in the study were included in the study. Patients were excluded if they were mentally incompetent, pregnant and lactating or if they suffer from Macrovascular complications in DM. All the collected relevant data's were assessed and were analyzed. Patient counseling was provided at the initial level and the patient knowledge about cause, risk, management, treatment and life style modifications of Diabetes mellitus were assessed during the Pre-counselling phase and Post-counselling phase. It has been reported that at least half of the diabetic elderly population do not realize that they have the disease. This study concludes that patient counseling by Pharmacists aids in the improvement of Quality of life of patients who are diagnosed and living with Diabetes Mellitus.

KEYWORDS: Patient compliance, Counselling, Glucose monitoring.

INTRODUCTION:
Diabetes mellitus (dm) is a group of metabolic diseases characterized by elevated glucose level resulting from defects in insulin secretion or action[1]. There are two subtypes in DM, namely type I or insulin dependent DM (IDDM) and type II or non-insulin dependent DM (NIIDM) [2].

Diabetes is a complex disorder which requires constant attention to diet, exercise, glucose monitoring, and medication to attain better glycemic control[3]. The main goals of diabetes care are good metabolic control, and minimization of complications which are modified by patient compliance - the extent to which a person's behavior coincides with medical or other health care regimen[4]. Patient's compliance can be determined by the accuracy, regularity and willingness that patients demonstrates in implementation of the prescribed therapeutic regimen in terms of taking medications, following diet, keeping appointments, and executing other lifestyle changes[5]. Many causes that may underlie poor compliance includes forgetfulness, poor

communication with physician, few symptoms, incidental chronic illness, perceived lack of effect, real or observed side-effects, ambiguous instructions or purpose of treatment.[6] This study was planned to determine improving patients compliance with blood glucose monitoring, dietary schedule and exercise in patients of DM. Poor adherence to medication regimens is common, contributing to substantial deterioration of disease, mortality and increased health-care costs. Hence, one can enhance adherence by enunciating the value of a patient's regimen, making the regimen less complicated and reorganizing the regimen to the patient's lifestyle[7]. Once the major factors relating to non-adherence are identified, intervention studies to improve adherence can be developed. These might include: 1)Improved patient-centred education enunciating self-management and consent for those with diabetes, 2) Health professional education, 3)The development of an adherence 'tool' for use in regular consultations and 4) Greater career involvement in medication management.

Low adherence to treatments has resulted in poor outcomes, even when the treatment was a placebo[8]. Effective ways to help people with diabetes to follow medical treatments could, importantly, have far greater effects on health than any treatment itself, largely because the results could be applied so broadly. Therefore, the purpose of this study is to identify adherence and reasons associated with Non-adherence to anti-diabetic therapy which will help the Physicians in making decisions to reduce the same, helps in achieving glycemic targets of diabetes mellitus patients. It will undoubtedly benefit the physicians and other health care professionals to understand the patient's response to the treatment provided which may help for a successful management of this chronic illness in the future.

METHODS:
A prospective observational study was conducted in a Tertiary care hospital, Chennai, Tamil Nadu, India. Patients demographic and laboratory investigation was collected from case sheets for a period of 1 year. The study was conducted after getting an approval from Institutional Ethical Committee (IEC/DOPI/2016/20). Patients were included in the study based on the following characters, 1)Patient who are diagnosed with diabetes mellitus with treatment of more than one medications, 2)Patient above 18 years of age, and 3)Patients who are willing to participate in the study were included in the study. Patients were excluded if they were mentally incompetent, pregnant and lactating or if they suffer from Macrovascular complications in DM. The enrolled patients were followed up during the study period and the relevant study data, including demographic details which contains age, gender and medical history were collected. All the collected relevant data's were assessed using MALMAS - Malaysian Medication Adherence Scale[9,10] (used to assess the level of medication adherence among the patients) and SF-12 questionnaire - which consists of 12 questions about the Physical and Mental components summaries respectively. They were analyzed using SPSS V20.0. The statistics that were used in the study were descriptive statistics (mean, standard deviation) and Student t-test to find the significance.

RESULTS AND DISSCUSSION:
A total of 200 patients were included in the study. Patient's demographics, patient medical history, lab investigations and other reports were monitored by using proforma. Assessment was done by using MALMAS and SF-12 Questionnaire respectively. Patient counseling was provided at the initial level and the patient knowledge about cause, risk, management, treatment and life style modifications of Diabetes mellitus were assessed during the Pre-counselling phase and Post-counselling phase.

TABLE 1: DEMOGRAPHIC CHARACTERISTICS OF THE STUDY SAMPLE

| DEMOGRAPHIC CHARACTERISTICS	NO.OF PATIENTS	PERCENTAGE
Gender		
Male	124	62%
Female	76	38%
Age		
18 – 35 years	15	8%
36 – 50 years	26	13%
51 – 65 years	62	31%
Above 66 years	97	48%
Socio-economic status		
Lower	154	77%
Middle	46	23%
Upper	-	-
Educational qualification		
Illiterate	53	26%
10th std	33	17%
Intermediate	91	46%
Graduate	12	6%
PG	11	5%
Social habits		
Smoker	35	17%
Alcoholic	36	18%
Both	24	12%
Tee-totaler	105	53%
BMI		
<18.5	8	4%
18.5 – 24.9	46	23%
25 – 29.9	88	44%
>30	58	29%
Employment status		
Employed	103	51%
Unemployed	32	16%
Retired	52	26%
Disabled	13	7%
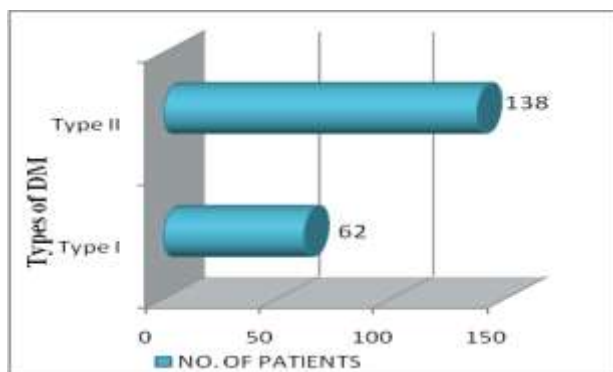
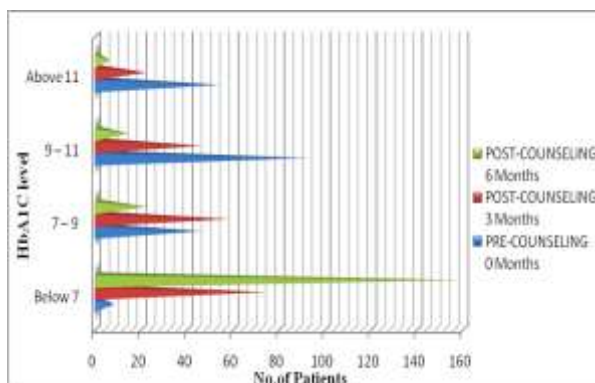**Figure 1: DISTRIBUTION BASED ON TYPE OF THE DISEASE**

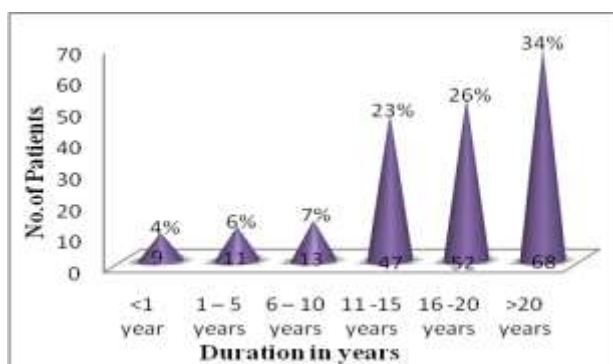**Figure 5: DISTRIBUTION BASED ON HbA1C LEVEL**

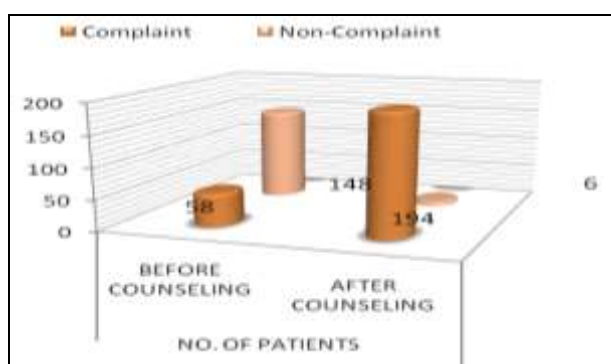**Figure 2: DISTRIBUTION BASED ON DURATION OF THE DISEASE**

Figure 6: COMPLIANCE STATUS BEFORE AND AFTER

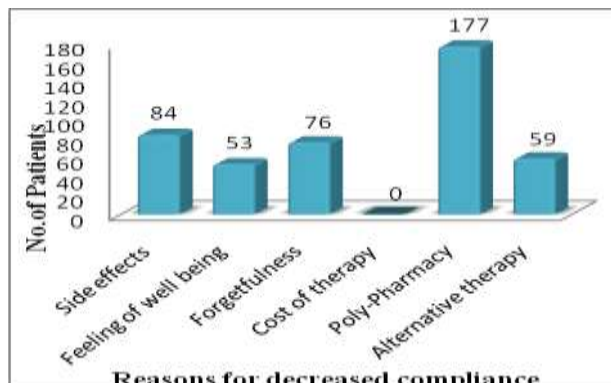**Figure 3: DISTRIBUTION BASED ON GENERAL HEALTH**

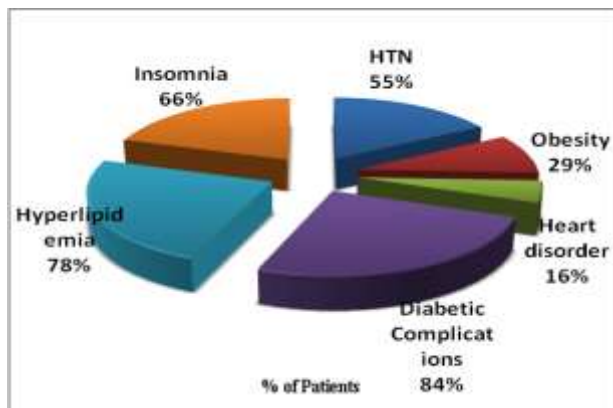**Figure 7: DISTRIBUTION ON REASONS FOR NON-COMPLAINCE**
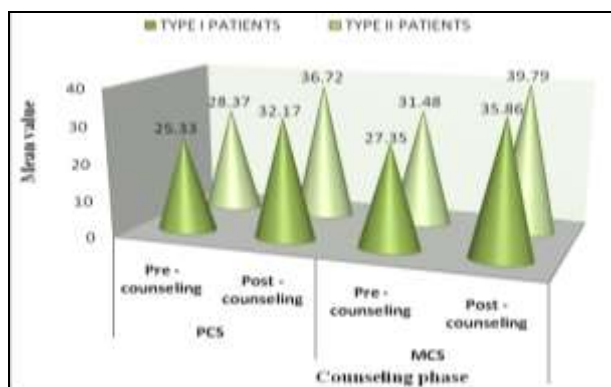

Figure 4: COMORBIDITIS

Figure 8: Comparison Of Pcs and Mcs Between Type I And Type Ii Dm Patients

- This study was designed to find out the Improvement of patient compliance in Diabetes Mellitus and to create awareness about the disease.In Gender wise distribution, the table 1 indicates that male patients (62%) are more prone to diabetes mellitus when compared to female patients (38%). In perious studies, it shows that Males predominated in the study population which is similar with the results of various other studies in India[11] and United States[12].

- Age wise distribution presented in table 1 indicates that a large number (48.5%) of patients aged above 65 years were diagnosed with DM, followed by 50-65 years (31%), 36-50 years (13%) and 18-35 years (7.5%), it indicates that majority of patients who were aged 50 and above (50-65 years : 62 patients in 200 patients and above 65 years : 97 patients in 200 patients) are diagnosed with DM compared to other age groups. In previous study also most of the patients diagnosed with DM were above the age group of 50[13].

- Out of selected 200 patients, 154 patients (77%) were lower class, 46 patients (23%) were middle class and there is no higher class patients since my study site was ESI hospital(Government based), this shows that patients who were diagnosed with DM are economically low in status in our study.

- Our study demonstrates that 53 patients (26.5%) were Illiterate, 33 patients (16.5%) were qualified with 1[0th] STD, 91 patients (45.5%) were qualified in intermediate, 12 patients (6%) are graduate and 11 patients (5.5%) are PG degree holders, it shows that educational qualification plays a major role in patients compliance towards DM. in previous study, it shows that Educational status was found more in primary education[14].

- Out of 200 patients, 62 Patients (31%) were found to have Type I DM and 138 patients (69%) were found to have Type II DM, this indicates that Type II patients were more prominent to non-compliance status in our study. But contradictory result were seen in previous study, that people who have longer duration of disease and Type 2 diabetes has more compliance[15].

- When the duration of the DM was taken into account, it was found that 9 patients (4.5%) had duration of <1 year, 11 patients (5.5%) had duration of 1 – 5 years, 13 patients (6.5%) had duration of 6 – 10 years, 47 patients (23.5%) had duration of 11 – 15 years, 52 patients (26%) had duration of 16 – 20 years, and 68 patients(34%) had >20 years of duration, it indicates that patients with longer durations like >11 years (ie, 11-15 years, 15-20 years and >20 years) are more prone to non-compliance in Diabetes Mellitus. But contradictory results were seen in previous study, it shows that most of the patients had a diabetic history of 1-5 years[16].

- Out of 200 selected patients, health condition was excellent in 11 patients (5.5%), very good in 33 patients (16.5%), good in 58 patients (29%), fair in 52 patients (26%) and poor condition in 46 patients (23%).

- It was observed that 35 patients (17.5%) were smoker, 36 patients (18%) were alcoholic, 24 patients (12%) were both smoker & alcoholic and 105 patients (52.5%) were Tee-Totaler, thus from our results it is concluded that DM is a metabolic disorder but it may also be exacerbated by social habits like smoking and drinking.

- Among the study population, 8 patients (4%) were underweight, 46 patients (23%) were in normal weight, 88 patients (44%) were over-weight and 58 patients (26%) are obese patients. Report shows that the great majority of them were either overweight or obese, which could be an outcome of lack of exercise, or a factor discouraging exercise. Similar results were shown by, Jin J., et al[17].

- Out of selected 200 patients, 110 patients (55%) were having HTN, 58 patients (26%) were having Obesity , 32 patients (16%) were having Heart disorders (like IHD, Angina, CAD, MI,etc), 167 patients (84%) were having Diabetic complications (like Diabetic foot ulcer, Diabetic retinopathy and CKD), 156 patients(78%) were having Hyperlipidimia and 132 patients (66%) are suffering with insomnia. In previous study, it was said that Comorbid conditions and a high level of medication usage affects compliance of Type II DM patients[18].

- We also categorized the patients of DM on the basis of their employment qualification. Among 200 patients, 103 patients (51.5%) were employed, 32 patients (16%) were Un-employed, 52 patients (26%) were retired, and 13 patients (6.5%) were Disabled. But contradictory results were seen in previous study, unemployed patients were more when compared to employed patients[14].

- HbA1C levels were observed at the beginning of the study (Before counseling) and at 3rd & 6th months (After counseling). 8 patients (4%) had HbA1C measure below 7% at first observation whereas it increased to 74 patients (37%) and 158 patients (79%) at 3rd & 6th months respectively, 46 patients (23%) had 7 – 9 level at first HbA1C measurement whereas it changed to 58 patients (29%) and 22 patients (11%) at 3rd & 6th months respectively, 92 patients (46%) had 9 – 11 level at first HbA1C measurement whereas it decreased to 46 patients (23%) and 14 patients (7%) at 3rd & 6th months respectively and 54 patients (27%) had level above 11 at first HbA1C measurement whereas it decreased to 22 patients (11%) and 6 patients (3%)

at 3rd & 6th months respectively, which shows that there is a gradual decrease in the level of Glycated Hb after counseling. Similar results were seen in a previously conducted study, Better medication adherence was also reported to be associated with lower HbA1c levels in patients who attended more intervening appointments in one year[19,20]. Schectman et al., who demonstrated that compliance contributes to a significant reduction of HbA1c[21]. Only few studies fail to confirm this finding[22].

- Malaysian Medication Adherence Scale (MALMAS) was used to assess the level of medication adherence among the patients who were non-adherent to their medication[9,10]. Statistical difference in MALMAS was determined using Student t-Test.

- In our study we observed that before counseling compliance status were only found in 52 patients and non-compliance were found in 148 patient whereas after counseling compliance status were seen in 194 patients and only 6 patients were found in non-compliance status. The compliance and non-compliance status were measured using MALMAS. Previous study shows that the most important factor contributing to compliance with diabetic regimen was the level of diabetes education provided about the basic knowledge of the disease, its causes, principles of drug therapy and complications of drug therapy[23].

- We demonstrated the reasons for non-compliance within the study population. It shows that non-compliance in 84 patients (42%) is due to side effects, 53 patients (26%) due to feeling of well being, 76 patients (38%) due to forgetfulness, then 177 patients (89%) due to poly-pharmacy, and 59 patients (29%) due to alternative therapy, and no patients were in non-compliance status due to cost effectiveness since my study took place in government hospital. It shows that the patients with poly-pharmacy leads to non –compliance in our study. In previous study, similar results have been shown. Adherence rate to diabetes medication can be influenced by the number of medication administered daily[24]. Rwegerera GM also found that patients reporting adverse effects was also a leading reasons for non-adherence[25]. In a study drugs brand unavailability and forgetfulness were major barriers for medications adherence[26].

- It has been reported that at least half of the diabetic elderly population do not realize that they have the disease[27].

- The Mean and SEM PCS and MCS were found using SF-12 questionnaire. The PCS and MCS were determined by Student t-Test. The Mean and SEM of PCS and MCS were 27.45 ± 3.46 and 31.57 ± 4.18 (0.05*) before counseling and 29.53 ± 3.75 and 37.51 ± 4.34 (0.05*) after counseling. The results indicate that PCS and MCS showed statistically significant difference after counseling. Similar results were also seen in other chronic illness.[28] The Mean and SEM of PCS and MCS were 25.33 ± 3.56 & 32.17 ± 4.15 and 27.35 ± 3.54 & 35.86 ± 4.31 before counseling and after counseling in Type I patients. The Mean and SEM of PCS and MCS were 28.37 ± 3.96 & 36.72 ± 4.53 and 31.48 ± 4.07 & 39.79 ± 4.79 before counseling and after counseling in Type II patients. When comparing the PCS and MCS in Type I and Type II patients, it shows that there is minimum variation in Type I and Type II DM patients. PCS showed statistically significant difference in Type I DM patients after counseling. PCS & MCS has been significantly improved in Type II DM patients.

CONCLUSION:
Diabetes mellitus is a metabolic diseases characterized by elevated level of glucose resulting from defects in insulin secretion or insulin action. Our study population of patients who were diagnosed with DM, both Type I and Type II, showed non-compliance/non-adherence but significant improvement was seen in compliance/adherence and also improvement in HbA1C level was also seen among the patients after providing patient education by Pharmacist, with the help of patient information leaflet. Assessment on the levels of knowledge and medication adherence among patients diagnosed with Diabetes mellitus should be carried out from time to time to ensure patient improvement and intervention effectiveness. This study concludes that patient counseling by Pharmacists aids in the improvement of Quality of life of patients who are diagnosed and living with Diabetes Mellitus.

ACKNOWLEDGEMENT:

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